HFI-35 purge/new

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

October 7, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Nancy Eckert
Chief Executive Officer
LifeSouth Community Blood Service
1221 NW 13th Street
Gainesville, Florida 32601

WARNING LETTER

Dear Ms. Eckert:

During an inspection of the Civitan Regional Blood System located at 502 South Enota Avenue, Gainesville, Georgia, on July 20 through August 2, 1999, our investigators documented violations of Sections 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to assure that personnel have the training and experience necessary for the competent performance of their assigned functions [21 CFR 606.20(b)] in that:

   a. Various personnel responsible for the collection of blood and blood components have preformed assigned task prior to receiving appropriate training and/or retraining.

   b. Several employees when tested in their specific job function failed one or more of the examinations, but were allowed to continue performing the task independently.

   c. There are no formal Training Standard Operating Procedures.

2. Failure to maintain detailed and accurate records [21 CFR 606.160(a)], in that:

   a. Hemapheresis records revealed the acceptance of a donor with a HCT value below 38%. Unit #W501140 was collected on 1/20/99 with a HCT value of 37%.

   b. Unit #W613451 collected 5/06/99 did not have a HCT value recorded on the flow sheet.

   c. Units #W500131, #W501281, and #W418682 collected 12/09/98, 8/28/98 and 7/15/98 respectively, did not have all vital sign values recorded on the flow sheet.

d. Records for approximately 300 Pheresis donors were unavailable for review, because the pink flow sheets and copies of Single Donor Records (SDRs) had been shredded.

e. Record/documentation review of the Apheresis Instrument History records for Apheresis machines ISO 3938, ISO 3239, and ISO 3244 disclosed entries that had been recreated or regenerated.

f. There were no QC records available for review for the Haemonetics Pheresis machines.

3. Failure to maintain equipment quality control [21 CFR 606.60 (a)] in that:

   a. Quality control procedures for copper sulfate were not being followed, and when observed was not performed correctly.

   b. Expired Hemotrol Reagents were used on several occasions.

   c. Failure to calibrate equipment (thermometer, ID #8) according to procedure.

   d. Several QC records were not reviewed and/or dated according to procedures.

   e. There were no manufacturer's manuals for the Donormatic scales and the Hemocue at the Center.

   f. Validation documentation records for several pieces of equipment were not available for review.

4. Failure to maintain and/or follow adequate written standard operating procedures [21 CFR 606.100(b)] in that:

   a. The Hemapheresis flowsheets and SDRs were not being completed according to procedures established.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation.

Please notify this office in writing by October 30, 1999, of the specific steps that you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed by October 30, 1999, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Barbara A. Wood, Director of Compliance, at the above address.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District

Cc: Ms. Rebecca L. Thomas
Branch Manager
Civitan Regional Blood System
d.b.a. LifeSouth Community Blood Center
502 South Enota Avenue
Gainesville, GA 30501-2546